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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,010	10/05/2000	Eva A. Turley	910130.401C1	5697

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05/15/2003

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

BEST AVAILABLE COPY

Office Action Summary

Application No.

09/685,010

Applicant(s)

TURLEY ET AL.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 and 38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1653

This is a new ground of restriction requirement. The previous restriction to the current invention mailed 25 February 2003 (Paper No. 21) has been vacated. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28 and 38, drawn to a method of treating a disease or disorder state comprising administering to a patient a biomolecule (a polypeptide or an antibody or a polynucleotide), classified in class 514, subclasses 2⁺ and 44, class 530, subclasses 300 and 387.1, class 536, subclass 23.1, class 436, subclass 86, class 435, subclasses 7.1, 320.1 and 325.
- II. Claims 29-33, drawn to an antibody that binds to the polypeptide, classified in class 530, subclass 387.1.
- III. Claims 34-36, drawn to a polypeptide comprising domains D1, D2, D3, D4, or D5 of receptor for hyaluronan-mediated motility (RHAMM), are classified in class 530, subclass 300, and 514, subclass 2⁺.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are patentably distinct from one another because of the materially different structures of the compounds claimed. Invention III (polypeptide) and Invention II (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Invention III (polypeptide) and Invention II (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions II and II are related to Inventions I as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, In the instant case, the polypeptide can be used in

Art Unit: 1653

proteinchip array to investigating signal transduction pathway, and the antibody can be immobilized on the chip-gold surface in surface plasma resonance technique in order to detecting real time protein-protein interaction, for example.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Additional Election Under 35 USC 121

It should be noted that this is not a species election but a part of the restriction requirement. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group, and indicate (2) the further election as required below.

Where Group I is elected, under 35 U.S.C. 121, applicant is also required to elect (A) one disease or disorder state; in particular, identify a particular disease or disorder state from claims 8-9, 12-14, 15-18, 21-24, and 27-28 since each disease or disorder state in the claims are different/distinct in its pathological mechanism and therapeutic treatment; (B) one biomolecule from polypeptide, antibody that binds the polypeptide, and a polynucleotide that encodes the polypeptide or the antibody thereof, wherein applicants are required to further elect a particular polypeptide molecule from the polypeptides: (i) a polypeptide comprising the peptide sequence BX7B with an appropriate sequence identifier, or, (ii) a polypeptide from the domain: D1, D2, D3, D4, or, D5 of RHAMM receptor molecule, and a particular antibody that specifically binds to the polypeptide molecule of (i) or from (ii), since each biomolecule to be elected is structurally different/distinct from one another. Applicant should identify the elections.

Where Group II is elected, applicant is required under 35 U.S.C. 121 to elect one antibody which binds to any one of polypeptides (domains) D1, D2, D3, D4, or, D5 of RHAMM with an appropriate sequence identifier and identify the claims readable thereon. Applicant should identify the elections.

Where Group III is elected, applicant is also required to specify the election under 35 U.S.C. 121 of one polypeptide molecule from the domains D1, D2, D3, D4, or, D5 of

Art Unit: 1653

RHAMM protein with an appropriate sequence identifier and identify the claims readable thereon. Applicant should identify the elections.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

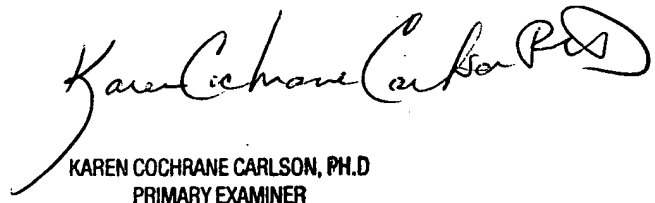
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1804 in the CM1 PTO Fax Center is (703) 308--4242 or 305-3014.



Samuel W. Liu, Ph.D.

May 8, 2003



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER